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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/772,672	02/05/2004	Robert Edward Burrell	14072-012002	5559

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EXAMINER	
PAK, JOHN D	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 09/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/772,672	BURRELL ET AL.	
	Examiner	Art Unit	
	JOHN PAK	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 90-113 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 90-113 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 5/31/05, 3/17/05, 5/7/04, 5/6/04, 2/5/04.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. 20060827
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claims 90-113 are pending in this application.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 90-113, drawn to a substrate coated with a water swellable gel coating, wherein the antimicrobial metals are selected from the group consisting of silver, gold, platinum and palladium and the substrate is/are catheters, cannula, endoscope, laparoscope, suture, staple, myringotomy tube, screw, joint, vascular graft, hernia mesh, guide wire, needle, pacemaker lead, perstaltic pump, shunt, implants.

II. Claims 90-113, drawn to a substrate coated with a water swellable gel coating, wherein the antimicrobial metals are selected from the group consisting of silver, gold, platinum and palladium and the substrate is/are wound or nasal packing, dressing, gauze, wound drain.

III. Claims 90-113, drawn to a substrate coated with a water swellable gel coating, wherein the antimicrobial metals are selected from the group consisting of silver, gold, platinum and palladium and the substrate is a condom.

IV. Claims 90-113, drawn to a substrate coated with a water swellable gel coating, wherein the antimicrobial metals are selected from the group consisting of silver, gold, platinum and palladium and the substrate is a contact lens.

V. Claims 90-113, drawn to a substrate coated with a water swellable gel coating, wherein the antimicrobial metals are selected from the group consisting of silver, gold, platinum and palladium and the substrate is a glove.

VI. Claims 90-95, 97-107, 109, 112, drawn to a substrate coated with a water swellable gel coating, wherein the antimicrobial metals are not silver, gold, platinum and/or palladium and the substrate is/are catheters, cannula, endoscope, laparoscope, suture, staple, myringotomy tube, screw, joint, vascular graft, hernia mesh, guide wire, needle, pacemaker lead, perstaltic pump, shunt, implants.

VII. Claims 90-95, 97-107, 109, 112, drawn to a substrate coated with a water swellable gel coating, wherein the antimicrobial metals are not silver, gold, platinum and/or palladium and the substrate is/are wound or nasal packing, dressing, gauze, wound drain.

VIII. Claims 90-95, 97-107, 109, 112, drawn to a substrate coated with a water swellable gel coating, wherein the antimicrobial metals are not silver, gold, platinum and/or palladium and the substrate is a condom.

IX. Claims 90-95, 97-107, 109, 112, drawn to a substrate coated with a water swellable gel coating, wherein the antimicrobial metals are not silver, gold, platinum and/or palladium and the substrate is a contact lens.

X. Claims 90-95, 97-107, 109, 112, drawn to a substrate coated with a water swellable gel coating, wherein the antimicrobial metals are not silver, gold, platinum and/or palladium and the substrate is a glove.

The ten inventions as set forth above are distinct for the reasons to follow. Groups I-V require the use of antimicrobial metals selected from the group consisting of Ag, Au, Pt, Pd, which are noble metals, classified in, inter alia, class 424, subclasses 618-619, 646, 649. Groups VI-X require the use of antimicrobial metals which are not noble metals, classified in class 424, 617, 630-645, 647-648, 650, et seq. Use of distinct metal substances is recognized separate subject for inventive effort. For example, U.S. Patent 7,018,411 is directed to a silver layer coating of medical devices. Groups I-V are thus distinct over Groups VI-X, respectively. Groups I, II, III, IV and V are distinct over each other because different substrates are involved. Group I is directed to medical devices, Group II is directed to wound related articles, Group III is directed to a condom, Group IV is directed to contact lens, and Group V is directed to gloves. Coatings related to such divergent substrates are distinct because of the divergent conditions under which each of the substrates must operate. Additionally, wound related articles (class 424, subclasses 446-447) and contact lens (class 424, subclass 429) have attained separate classification status. Distinctness of Groups VI, VII, VIII, IX and X over each other is analogous.

Further, to search and examine more than one invention group would place an undue burden on the Examiner. The scope, and hence the search burden, of any one invention group is already quite substantial. There are more than 1,400 patent documents in classes 424 and 514 that recite silver in the claims. Note, this is just for silver, let alone the rest of the metal substances covered by each of the inventions. Not only would the search for more than one type of metals place a serious burden on the Examiner, the search for more than one type of substrates with such metals would also place a serious burden on the Examiner. Technology directed to coating the various divergent medical devices or articles is distinct in the absence of a nexus type art, and a search for one type of medical devices or articles would be woefully incomplete as a search for the other type of medical devices or articles. For these reasons, the search and examination of more than one invention group would place an undue burden on the Examiner if the restriction were not required.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02) and are separate subjects for inventive effort, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

During a telephone conversation with Mr. Daley on 8/28/2006 a provisional election was made with traverse to prosecute the invention of Group I, claims 90-113, to the extent that the antimicrobial metals are selected from the group consisting of silver, gold, platinum and palladium and the substrate is/are catheters, cannula, endoscope, laparoscope, suture, staple, myringotomy tube, screw, joint, vascular graft, hernia mesh, guide wire, needle, pacemaker lead, perstaltic pump, shunt, implants. Affirmation of this election must be made by applicant in replying to this Office action.

Claims 90-113 will presently be examined to the extent that they read on the elected subject matter.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 90-113 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burrell et al. (US 5,681,575) in view of Fan (WO 00/44414).

Burrell et al. disclose antimicrobial metals such as silver, gold, platinum and palladium in powder form (column 5, lines 41-44), which are formed with sufficient atomic disorder so that atoms, ions, molecules or clusters of the antimicrobials are released into an alcohol or water based electrolyte on a sustainable basis, including concentrations in body fluids of less than about 0.5-1.5 µg/ml (column 5, lines 49-53 & column 8, lines 52-54). Composite materials formed by including oxygen with the metal are disclosed (column 6, lines 47-49; column 9, lines 57-61; column 10, line 29). Broad particle size is disclosed, including nanocrystalline powders to flakes (column 4, lines 33-35; column 10, line 25) and an example of 30 nm silver nanocrystalline powder (column 15, line 52). Medical devices carrying or coated with the antimicrobial powders or coatings are disclosed, including incorporation of the antimicrobial powders into creams, polymers, paints or other matrices (column 6, lines 10-24 & column 10, lines 37-42). Disclosed medical devices include catheters, implants, tracheal tubes, orthopedic pins, shunts, connectors, prosthetic devices, pacemaker leads, needles, surgical instruments, ventilator tubes (column 7, lines 24-36).

Fan discloses improved lubricious medical devices such as, for example, catheters, guide wires, endotracheal tubes and implants, which incorporate active ingredients such as virucides, antimicrobials (page 3, second and third paragraphs; pages 4-6). Silver and its compounds are exemplified (page 6, lines 14-17), as are a diverse list of active ingredients such as hormones (page 4, line 17) and antimicrobials

(page 6, third paragraph). Suitable lubricious polymers are polymers that become substantially more lubricious when wetted with an aqueous liquid than when dried (page 6, last paragraph), and such polymers include water-swellable polymers, which are hydrophilic polymers that absorb sufficient water to render it lubricous in the hydrated state (page 7, lines 1-4). Carboxymethyl cellulose (page 8, lines 2 & 8), polysaccharides (page 7, line 12) are disclosed.

Although Burrell et al. disclose the claimed antimicrobial silver, gold, platinum and palladium metals formed as nanocrystalline powders with sufficient atomic disorder, and claimed medical devices carrying or coated with said antimicrobial powders, including incorporation of said powders into creams, polymers, paints or other matrices, Burrell et al. do not expressly disclose a water-swellable gel coating of said powders. However, Fan teaches the advantages of using water-swellable coatings on the same or similar medical devices for sustained delivery of antimicrobials such as silver compounds (page 3, second and third paragraphs & page 6, line 14-17). As a result, the ordinary skilled artisan would have been motivated to incorporate the nanocrystalline, antimicrobial, atomically disordered metals of the elected invention, as taught by Burrell et al., into polymers/matrices, the specifics of which are fairly suggested by Fan, who provide the motivation to utilize the claimed lubricious polymers such as carboxymethyl cellulose.

Regarding the size parameters of claims 99-104, the ordinary skilled artisan, upon being taught by Burrell et al. that "broad particle size" are suitable (column 4, lines 33-35), including nanocrystalline powders and 30 nm silver nanocrystalline powder, would have been motivated to utilize the range of grain size and particle size of the powder, as claimed by applicant. Small grain size is specifically disclosed by Burrell et al. as "an important cofactor" that produces the desired antimicrobial effect (column 16, lines 51-54). As particle size of the powder is comprised of many crystals of the metals, the larger micrometer size range of the powder particle size would have been obvious to the ordinary skilled artisan.

Claims 105-107 are noted for reciting specific weight percentages of the antimicrobial metals in the coating. Such amount ranges are held to be within the skill of the ordinary skilled artisan in the field. Not only is a metal such as silver extremely well known for possessing excellent antimicrobial properties, Burrell et al. teach improved antimicrobial efficacy due to the sufficient atomic disorder and concentrations in body fluids of less than about 0.5-1.5 μg/ml. With such teachings, the ordinary skilled artisan would have been motivated to arrive at the claimed concentration ranges through routine experimentation, wherein such concentration ranges would have been expected to perform the very function that an antimicrobial substance is selected to do, i.e. deliver antimicrobial efficacy.

Claims 109-111 recite including various additional agents such as preservatives, hormones, thickeners, methyl paraben. It is the Examiner's position that delivery of additional active agents to a patient in need thereof via the delivery of medical devices is obvious because the very application of the medical device presents a delivery means. Fan's disclosure is evidence of this, and Fan fairly suggests applicant's additional agents, including a common antimicrobial such as paraben compounds.

Claims 112-113 recite less than 0.01 wt% inclusion of various ingredients, but in view of no disclosure in the prior art that necessitates their inclusion and in the absence of objective evidence of nonobviousness to the contrary, the ordinary skilled artisan in this field would have been motivated to arrive at the claimed coated substrates without such ingredients because the prior art does not require their presence.

Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly disclosed or suggested by the teachings of the cited references.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to JOHN PAK whose telephone number is **(571)272-0620.** The Examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE, Johann Richter, can be reached on **(571)272-0646**.

The fax phone number for the organization where this application or proceeding is assigned is **(571)273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JOHN PAK
PRIMARY EXAMINER
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